

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:1159
ANSWERED ON:08.12.2004
IMPLEMENTATION OF SCHEDULE M
Shakya Shri Raghuraj Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government has received representations from various quarters to form committee to go into the genuine difficulties of small scale units for implementation of Schedule M;
- (b) if so, whether the prices of medicines will go up if provisions of schedule M are implemented and many tiny and small scale drug units will face closure if hasty implementation of Schedule M is made; and
- (c) if so, the action taken by the Government thereon?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (c): Yes, Sir. Revised Schedule M to the Drugs and Cosmetics Rules, 1945 came into force in December, 2001 after publication in official Gazette. However, the manufacturers licensed prior to 11th December, 2001 were given an exemption upto 31st December, 2004 for the implementation of the provision of Schedule M. The Schedule is being further rationalized on the basis of the representations received and a Gazette Notification GSR 738 (E) dated 8.11.2004 has been published for comments. The defective of implementation of Schedule M is to achieve uniform standardization and production of quality drugs in the country, rather than price regulation.